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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,340	12/10/2001	Herath Mudiyanselage Athula Chandrasiri Herath	9195-078	1525

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EXAMINER	
TURNER, SHARON L	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,340	HERATH ET AL.	
	Examiner	Art Unit	
	Sharon L. Turner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 9-25-02.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restriction

1. Claims 1-57 are pending.

Improper Markush

2. Prior to setting forth the restriction requirement, it is pointed out that applicants have presented instant claims in improper Markush format, see Ex parte Markush, 1925 C.D. 126, In re Weber, 198 USPQ 334 and MPEP 803.02 and 806.04. The claims are improperly set forth as the genus claims encompassing multiple products (ADPI's), as identified and claimed, fail to share the characteristics of a genus, i.e., a common utility and a substantial structural feature essential to the disclosed utility. Alternatively, the claims define multiple structurally distinct compounds capable of different use, with different modes of operation, different function and different effects. A reference against one of the claimed components or methods would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims define inventions which are not proper species.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 in part drawn to a method of screening via analysis of test sample and abundance, classified for example in class 204, subclass 450.

II. Claims 8-11 in part drawn to a method of screening via analysis of test sample and antibody detection, classified for example in class 435, subclass 7.1.

III. Claims 12-15 in part drawn to a peptide preparation, classified for example in class 530, subclass 350.

IV. Claims 16-22 in part drawn to antibodies, classified for example in class 530, subclass 387.1.

V. Claim 23 in part drawn to a method of treating or preventing with an antibody, classified for example in class 424, subclass 130.1.

VI. Claims 24 in part drawn to a method of treating or preventing with a peptide, classified for example in class 514, subclass 2.

VII. Claims 25-26 in part drawn to a method of treating or preventing with a nucleic acid, classified for example in class 514, subclass 44.

VIII. Claims 27-29 and 38 in part drawn to a method of screening in vitro via interaction or binding, classified for example in class 435, subclass 5.

IX. Claims 30-31 in part drawn to a method of screening in vitro via induction of second messenger, classified for example in class 435, subclass 7.6.

X. Claims 32-37 in part drawn to a method of screening in vivo, classified for example in class 800, subclass 21.

XI. Claims 39-41 in part drawn to a method of screening in vitro via ADPI activity, classified for example in class 435, subclass 7.4.

XII. Claims 42-44 in part drawn to a method of screening in vitro via nucleic acid, classified for example in class 435, subclass 6.

XIII. Claims 45 in part drawn to a method of modulating ADPI activity, classified for example in class 424, subclass 198.1.

XIV. Claims 46-48 in part drawn to an agent that modulates ADPI, classified for example in class 536, subclass 23.1.

XV. Claim 49 in part drawn to a method of treating with an ADPI agent, classified for example in class 514, subclass 12.

XVI. Claim 50 in part drawn to a method of modulating disease, classified for example in class 800, subclass 3.

XVII. Claims 51-55 in part drawn to a method of screening via ERK-2 activity, classified for example in class 435, subclass 7.4.

XVIII. Claims 56-57 in part drawn to a method of screening via Erk-2 binding, classified for example in class 435, subclass 7.1.

4. The inventions are distinct, each from the other because of the following reasons:

5. Inventions III, IV, and XIV are related as products. The products are distinct each from the other as the products are comprised of divergent structure, effects and function, for example nucleic acids, peptides, antibodies, organic and inorganic agents.

6. Inventions I-II, V-XIII, and XV-XVIII are related as processes. The processes are distinct each from the other as the processes differ in reagents, steps, functions and effects. The different methods alternatively use nucleic acids, peptide, antibodies, organic and inorganic agents. Some of the methods are in vitro while others are in vivo. Moreover each of the methods differs in contacting and assessment steps, for example binding, activity, modulation of disease, and induction of second messenger systems.

7. Inventions (III-IV and XIV) and (I-II, V-XIII, and XV-XVIII) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the products as claimed can be practiced with another materially different product or (2) the products as claimed can be

used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the nucleic acids, peptides, antibodies, organic and inorganic compounds can be practiced with alternative nucleic acids, peptides, antibodies, organic and inorganic compounds (as further evidencded by the claims) and the products as claimed can be used alternatively in various methods (as further evidenced by the claims) including, a method of treatment, a method of making antibodies, a method of screening compounds, and a method for detecting compositions, a method of assessing diagnosis, modulating disease and assessing binding and activity.

8. Similar to the notations with respect to Ochiai and Brouwer noted below, claims 12-22 and 46-48 directed to distinct ADPI's link(s) inventions related to the methods of making and using the ADPI's. The restriction requirement amongst the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44

F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01

9. Furthermore, in addition to the election of one of the above XVIII groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiments to which the claims will be restricted in accordance with the elected group:

A single designated ADF selected from the Alzheimer's Disease-Associated Features (ADFs) listed in claim 5

and ;

A single designated ADPI selected from the Alzheimer's Disease-Associated Protein Isoforms (ADPI's) listed in claims 7, 12, 16, 24, 25, 42, 43, 45, 46, 49 and 50.

10. The inventions are distinct, each from the other because of the following reasons:

11. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products indicated as A-B constitute patentably distinct inventions for the following reasons. Each of the features, polynucleotides, polypeptides and antibodies has a unique structural feature which requires a unique search of the prior art. The inventions indicated differ in structure and function as they are composed of divergent nucleic and amino acids and are differentially able to hybridize, bind and/or mediate bological functions. A reference to one element would not constitute a reference to another. In addition, searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-

extensive.

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

13. Because these inventions are distinct for the reasons given above and the search required for any Group is not required for any other Group, restriction for examination purposes as indicated is proper.

14. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-XVIII and a single Alzheimer's Disease-Associated Feature and Alzheimer's Disease-Associated Protein Isoform to which the claims will be restricted, even though the requirement is traversed. Applicant is advised that neither I-XVIII nor the noted features and protein isoforms are species election requirements; rather each is a restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups. No evidence is of record that any of the features share structure and/or function and each of the features and isoforms as claimed are separately useable.

16. Applicant is reminded that upon the cancellation of claims to a non-elected

invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

17. Similarly and as noted above with respect to linking claims, the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process

Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

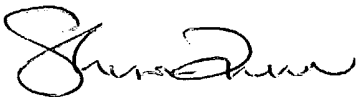
18. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.



SHARON L. TURNER, PH.D.
PATENT EXAMINER

Sharon L. Turner, Ph.D.
September 30, 2004